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Governor

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Lt. Governor

## New Jersey Office of the Attorney General

Division of Consumer Affairs  
Board of Pharmacy  
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### BOARD OF PHARMACY MINUTES OF THE OPEN SESSION SOMERSET CONFERENCE ROOM, 6<sup>th</sup> FLOOR OCTOBER 24, 2012

#### I. CALL TO ORDER

The Open Meeting of the New Jersey Board of Pharmacy was called to order by Board President Edward McGinley in the Somerset Room, 6<sup>th</sup> Floor at 124 Halsey Street, Newark, on October 24, 2012 at 9:06 a.m. All members were duly notified of the time, place and all pertinent materials were provided to members.

#### II. SUNSHINE LAW ANNOUNCEMENT

President Edward McGinley, read a statement that the newspapers and appropriate elected officials had been notified of the meeting according to the requirements of the Open Public Meetings Act N.J.S.A., Chapter 231, PL 1975, C.10:4-8.

#### III. ROLL CALL

Edward G. McGinley, R.Ph.  
Thomas Bender, R.Ph.  
Margherita Cardello, R.Ph.  
Marc Sturgill, R.Ph.  
Richard Palombo, R.Ph.  
Stephen Lieberman, R.Ph.  
Mahesh Shah R.Ph.

President  
Vice President; late arrival, 9:08 a.m.  
late arrival, 9:42 a.m.

#### OTHERS IN ATTENDANCE

Anthony Rubinaccio  
Linda Brodie  
Matthew Wetzel  
Megan Cordoma  
Michael Westenberger

Executive Director  
Customer Service Rep I  
Government Rep  
Deputy Attorney General  
Enforcement Bureau

#### IV. UPDATES BY EXECUTIVE DIRECTOR

The Executive Director reported for the month of September, \$12,375 was collected in fines and penalties. The following permits, licenses, and registrations were issued during the month of September:

- Technicians – 187
- Pharmacists – 123 (116 by examination/score transfer, 7 by reciprocity)
- Out-of-state pharmacies – 10

- In-state pharmacies – 3
- Pharmacists receiving immunization approval – 122
- Interns (Foreign graduates) – 9

Additionally, from October 14 through 16, the National Association of Boards of Pharmacy (NABP) District 1 and 2 met in Skytop, Pennsylvania to discuss a variety of topics including collaborative practice regulations and the impact of the Affordable Care Act on patients and pharmacists and a resolution to modify the five (5) percent (%) wholesaler rule for pharmacies. The main topic of discussion was compounding pharmacies and the accreditation of those pharmacies. Director Rubinaccio was elected to be the District 2 Representative on the NABP Resolutions Committee. All states in District 1 and 2 were in attendance except the District of Columbia and Maine; New Jersey was represented by Board Members: Edward McGinley, Thomas Bender, Margherita Cardello and Richard Palombo and Executive Director: Anthony Rubinaccio.

## V. OLD BUSINESS

- 1) Francesco Taddeo, on behalf of his client, **Jeffrey Strougo, R.Ph** – Requesting reinstatement of license

Francesco Taddeo, on behalf of his client, Jeffrey Strougo, R.Ph., is requesting the reinstatement of Mr. Strougo's pharmacist license in accordance with his Interim Consent Order that was filed on February 22, 2012.

Thomas Bender moved, seconded by Marc Sturgill, that before Mr. Strougo can be reinstated the following documentation is requested: 1) proof that Mr. Strougo has successfully completed Pre Trial Intervention; 2) recommendation from the Professional Assistance Program of New Jersey (PAP) regarding follow-up treatment and any restrictions; and 3) take the Pharmacist Assessment for Remediation Evaluation (PARE) exam. Mr. Strougo shall submit all the above items to the Board office for review and consideration. The Board may request an appearance by Mr. Strougo. **Motion passed 5-0**

Note: The Pharmacist Assessment for Remediation Evaluation (PARE) is a multi-dimensional assessment that the Boards of Pharmacy may use as an auxiliary tool when making decisions regarding pharmacist practice deficiencies that are due to noncompliance with pharmacy practice standards, laws or regulations, and result in compromises to patient safety. The PARE assessment is computer-based and consists of 210 multiple choice questions that cover three domains: medication safety and the practice of pharmacy; professional ethics/pharmacist judgment; and clinical pharmacy practice.

- 2) Angelo J. Cifaldi, on behalf of his client, **Nick Stamatiadis, R.Ph** – Requesting reinstatement of license

Angelo Cifaldi, on behalf of his client, Nick Stamatiadis, R.Ph., is requesting the reinstatement of Mr. Stamatiadis's pharmacist license in accordance with his

Consent Order that was filed on November 15, 2011.

**Chair Direct:** This matter was tabled until a future Board meeting until all requested documents are received from Angelo J. Cifaldi and his client, Nick Stamatiadis, R.Ph.

3) **Fred Burlakoff, R.Ph** – Requesting modification of Consent Order

Fred Burlakoff, R.Ph., submitted correspondence to the Board requesting reinstatement of his pharmacist license in accordance with his Consent Order which was filed on November 9, 2011.

The Board reviewed the documents that Mr. Burlakoff submitted and Thomas Bender moved, seconded by Stephen Lieberman to: 1) have Mr. Burlakoff take the Pharmacist Assessment for Remediation Evaluation (PARE) exam; and 2) keep the Board apprised of any change in status of the Georgia Consent Order. Upon completion of the PARE assessment, the Board may request Mr. Burlakoff to appear before the Board to show competency to return to the pharmacy practice. **Motion passed 6-0**

4) **Hackettstown Regional Medical Center** – Requesting waiver to ISO Class 6 for clean room

Mark Harris appeared before the Board on October 3, 2012 in order to mitigate Hackettstown Regional Medical Pharmacy's citation for not having a chemotherapy clean room and non-chemotherapy clean room certified as an ISO Class 6; both clean rooms were certified as ISO Class 7 environments. The Board suggested that Mr. Harris submit to the Board a request for a waiver to ISO Class 6 clean room environment, since the Board is in the process of updating its regulations to require an ISO Class 7 environment.

Richard Palombo moved, seconded by Marc Sturgill to grant Hackettstown Regional Medical Center a waiver to N.J.A.C. 13:39-11.19(d).

**Motion passed 6-0**

5) **Medco Health Solutions of Franklin Lakes** – Presentation before the Board to seek amendment to work at home pilot program

John Sisto and Sal Anselmi of Medco Health Solutions/Express Scripts appeared before the Board to discuss a modification to their current work at home pilot program. Medco Health Solutions would like to change its current pharmacist and technician authentication method of fingerprint identification and use a Virtual Private Network (VPN) secure ID Token authentication method. Mr. Sisto explained the reason for the request was due to the fact that fingerprint readers and software have become commoditized and there is a lack of IT support by the fingerprint reader companies to keep the software up to date and working with Medco's programs. Mr. Anselmi explained that a pharmacist/technician will have to: 1) log-in to the computer terminal with a username & password; then 2)

log-in to Citrix, and then to begin processing prescriptions; and 3) log-in to the VPN by entering a string of randomly generated numbers, which change every 90 seconds, on the ID Token plus enter 4 digits which are known only to the user. In order to successfully log-in the random digits and user unique digits must match. An inactivity auto-log-out feature is used in case a pharmacist/technician walks away from their computer. Mr. Sisto noted that Ohio is the latest state to allow the VPN Token method in addition to Arizona, Virginia and Texas, which have allowed the VPN Token for several years.

Marc Sturgill moved, seconded by Mahesh Shah to amend Medco's existing work at home pilot program to allow for a VPN Token authentication method in place of the biometric, fingerprint authentication. Richard Palombo was recused because he is employed by Medco. **Motion passed 6-0**

- 6) Ned Milenkovich, on behalf of his client, **Rexam Prescription Products Inc., a.k.a. "Rexam"** – Gave a presentation before the Board regarding prescription drug container safety

Ned Milenkovich of McDonald Hopkins, representing Rexam, and David Sanford of Rexam appeared before the Board to discuss prescription drug container safety and measures that the Board could take to protect the public from potential harm. Mr. Sanford informed the Board about the current USP 671 guidelines concerning moisture permeation and light transmission of prescription containers. He presented examples of the top 20 drugs dispensed in 2010 and all of them required a dispensing container that was tight, light resistant, or a combination of both. Thomas Bender noted that he was on the USP Packaging Committee and that drugs are packaged by the manufacturer in accordance with USP 671, but once the medication is dispensed to the patient, state regulations on container safety take over. Mr. Milenkovich provided the Board with a copy of a Ferris State University study that conducted moisture permeation and light transmission testing on ten types of prescription vials. Mr. Milenkovich and Mr. Sanford highlighted New Jersey's current regulations, specifically, 13:39-5.8(a)12, which require a pharmacy to stock prescription containers that meet USP standards on "light resistance and tightness". They suggested a more specific definition for prescription containers in the New Jersey regulations.

**Chair Direct:** The Board asked Mr. Milenkovich to submit rules and regulations from other states to be considered by the Board Rules & Regulations Committee. Mr. Milenkovich agreed to submit. Also Marc Sturgill will include an article about the USP 671 and Container Integrity in an upcoming newsletter to help educate New Jersey pharmacists.

## **VI. NEW BUSINESS**

- 1) **Parul R. Patel** – Waiver for TOEFL

Parul Patel is applying for a New Jersey pharmacist license by reciprocity and is

requesting the Board to waive the TOEFL exam. Ms. Patel has until December 31, 2012 to pass the TOEFL exam and become FPGEC certified. Ms. Patel is a licensed pharmacist in New York over the past 4 years and states that she has been unable to take the TOEFL exam due to her busy schedule.

Margherita Cardello moved, seconded by Richard Palombo to deny the waiver for the TOEFL exam, because no valid medical reason was provided to the Board which prevents the applicant from passing the TOEFL exam. Thomas Bender was recused because the applicant works for Duane Reade/Walgreens which is a conflict of interest. **Motion passed 6-0**

- 2) **Pensacola Pharmacy** – Out-of-state pharmacy seeking waiver to allow a pharmacist to be available by cell phone for consultations on Saturdays

Pensacola Apothecary is a compounding pharmacy that is considering applying for an out-of-state pharmacy registration in New Jersey. The pharmacy is only open five (5) days a week, Monday through Friday, and in order to be in compliance with N.J.S.A. 45:14-7.3 the pharmacy has asked the Board for a waiver to the requirement to have a pharmacist available by phone “*not less than six days per week.*” Pensacola would have a pharmacist available on Saturday via the toll-free number that would be automatically forwarded to a cell phone.

Stephen Lieberman moved, seconded by Thomas Bender to deny the waiver because the Board has concerns that the pharmacist may not have access to patient records. **Motion failed 4-3**; Voting in the affirmative: Thomas Bender, Stephen Lieberman and Marc Sturgill; Voting in the negative: Mahesh Shah, Edward McGinley, Richard Palombo and Margherita Cardello.

Richard Palombo moved, seconded by Thomas Bender to contact the applicant and obtain information on how the patient profiles/records will be accessed by the pharmacist when taking calls via cell phone and why a cell phone will be used instead of a landline. **Motion passed 6-0**

- 3) **Review & Comment on Legislative Bills**

a. **S2280 (Sen. Weinberg)**, requires monitoring of prescriptions for human growth hormones (HGH). The legislation would require pharmacies to include HGH in their reporting to the Prescription Drug Monitoring Program (PMP). Currently, under a directive from the DCA Director’s office, the PMP already requires HGH reporting under the PMP. To date there have been under 13,000 HGH prescriptions filled, out of a total of 13 million reported prescriptions.

Stephen Lieberman moved, seconded by Edward McGinley for the Board to take a position of non-support for S2280 because HGH is already being monitored and reported to the PMP. **Motion passed 7-0**

b. **A3251 (Asm. Ramos)**, permits pharmacists to administer vaccines to children

14 years of age or older. The legislation would lower the age limit from the current 18 years of age to 14 years of age. The age minimum in surrounding states are: Delaware, 12 years of age, New York and Pennsylvania are 18 years of age.

Thomas Bender moved, seconded by Richard Palombo for the Board to take a position of support for A3251 and recommend the legislation lower the age limit to 12 years of age or older, which is in line with the Food and Drug Administration's (FDA) definition of an adolescent. **Motion passed 7-0**

- c. **A3394 (Asm. Caputo)**, authorizes professional and occupational boards to recognize continuing education approval entities. The Board already has regulations that address continuing education (CE) credits in N.J.A.C. 13:39-3A.1 through 13:39-3A.7.

Marc Sturgill moved, seconded by Thomas Bender for the Board to take a position of support for A3394 to the extent that the legislation duplicates current Board of Pharmacy regulations under N.J.A.C 13:39 Subchapter 3A. **Motion passed 7-0**

- d. **A3395 (Asm. Kean)**, requires compounding pharmacies be accredited by Pharmacy Compounding Accreditation Board. The Board has several concerns with language in the legislation, starting with the definition of a compounding pharmacy. The bill states "a licensed pharmacy operating in this State that engages in the preparation of sterile or nonsterile compounded formulations for dispensing..." The definition as written is too broad, because it would include all pharmacies in the State and not capture only those pharmacies which have compounding operations. Secondly the Board has concerns that since the Pharmacy Compounding Accreditation Board (PCAB) is the only organization that provides this service and by specifically naming PCAB, it would monopolize the market and there are concerns that PCAB wouldn't have the personnel to be able to oversee this accreditation in a timely fashion. Lastly, the Board is unsure how and why the Department and Commissioner of Health are involved in the oversight of compounding pharmacies, since the Board of Pharmacy regulates all pharmacies

Marc Sturgill moved, seconded by Richard Palombo for the Board to take a position, expressing the above concerns for A3395. **Motion passed 7-0**

#### 4) **Draft Centralized Prescription Handling Application**

The central fill application has been revised and updated in order to more clearly capture the essential information as required by N.J.A.C. 13:39-4.19. One of the major changes to the application is the requirement for all parties involved in the central fill process to provide the Board with a copy of the signed and executed service agreement. Also each pharmacy in the agreement must indicate which

part of the central fill process they are fulfilling. Once approved, the new central fill application will be used going forward for all future applicants.

The Board accepted the application as informational.

**VII. MITIGATION/HEARING REQUEST**

**VIII. INFORMATIONAL**

**IX. COMMITTEE REPORTS**

**X. APPROVAL OF MINUTES FOR OCTOBER 3, 2012**

Thomas Bender moved, seconded by Marc Sturgill to approve the October 3, 2012, Open Session Minutes as amended. **Motion passed 7-0**

**XI. ADJOURNMENT**

At 11:12 a.m. Marc Sturgill moved, seconded by Margherita Cardello, to adjourn the Public Session and move into the Executive Session for review of 3 Complaints, 4 Old Business Items, 14 New Business Items, the Secretary's Report and Recommendation on Retail and Institutional Permits, 1 Investigative Inquiry and the approval of the October 3, 2012, Executive Session Minutes.